

Serial No 09/581,967, filed June 19, 2000
Docket No. 1103326-0624
Page 2 of 5

IN THE CLAIMS:

Replace claim 29 with the corresponding amended claim below:

29. (Thrice amended) A pharmaceutical formulation comprising therapeutically effective amounts of an IBAT inhibitor compound and a bile acid binder, wherein the bile acid binder is coating layered for targeted release of the bile acid binder in the colon.

REMARKS

Applicants are grateful for the allowance of claims 29 and 33-45. A Notice of Allowability issued in the referenced application on March 17, 2003. An Interview Summary and Examiner's Amendment are attached to the Notice of Allowability.

By this Amendment, claim 29 has been amended to place the claim in the same form as it was prior to entry of the Examiner's Amendment. Support for the amendment to claim 29 is provided by the specification at page 5, lines 11-13 and 19-21.

As noted in the Interview Summary, a telephonic interview between the Examiner and the undersigned Attorney occurred on March 11, 2003. During the course of that discussion, the Examiner indicated that there was a "possible" indefiniteness issue with respect to claim 29 since the claim did not recite the release site of the IBAT inhibitor. In the spirit of cooperation and to advance the application to allowance, Applicants' Attorney authorized the amendment to claim 29 to recite that the IBAT inhibitor is formulated for delivery in the lumen.

Upon further consideration, Applicants respectfully submit that the authorized amendment to claim 29, as entered by the Examiner's Amendment, is not necessary for either formal or prior art reasons. With respect to the prior art, the issuance of a Notice of Allowability is an affirmation that the prior art does not disclose or suggest the invention of allowed claims 29

Serial No 09/581,967, filed June 19, 2000
Docket No. 1103326-0624
Page 3 of 5

and 33-45 wherein the bile acid binder is released in the colon. A recitation of the target site of the IBAT inhibitor has no effect on this patentably distinguishing feature, i.e., the release site of the bile acid binder, which is the special technical feature linking all of allowed claims 29 and 33-45. As such, there is no indefiniteness issue with respect to claim 29 which recites the release site of the bile acid binder but does not recite the target site of the IBAT inhibitor. In contrast, claim 33 recites the respective release sites of the two active ingredients. Accordingly, there is no overlap in scope of the embodiments of claims of 29 and 33.

For all of the foregoing reasons, Applicants submit that the authorized amendment of claim 29, as entered by the Examiner's Amendment, unduly limits the scope of patent protection to which Applicants are entitled in view of application as originally filed and in view of the prior art. The Examiner's characterization of "possible" indefiniteness issues with claim 29, as noted in the Interview Summary, indicates that there may not indeed be any indefiniteness issue and that the authorized amendment was unnecessary.

The Examiner's reconsideration is appreciated. Withdrawal of the authorized amendment with respect to claim 29 is requested to return that claim to its form prior to entry of the Examiner's Amendment.

FROM W&C LLP 19TH FL

(THU) 3.27'03 0:01/S...23:59/NO. 4260454880 P 6

Serial No 09/581,967, filed June 19, 2000
Docket No. 1103326-0624
Page 4 of 5

CONCLUSION

Upon entry of this Amendment, claims 29 and 33-45 remain pending. Applicants respectfully submit that claims 29 and 33-45 remain in condition for allowance for the reasons of record. Prompt issuance of a Notice of Allowance is earnestly solicited.

The Assistant Commissioner is hereby authorized to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: 27 March 2003

Respectfully submitted,

John M. Genova
John M. Genova
Reg. No. 32,224
Attorney for Applicants

Customer No. 007470
White & Case LLP
Attorney's Direct Dial: (212) 819-8832

- 4 -

NWY/DOCX 1020338 v1 (Jmg/M01.DOC) (25)

03/27/03 THU 12:58 [TX/RX NO 8974] 006

FROM W&C LLP 19TH FL.

(THU) 3.27' 03 0:02/23:59/NO. 4260454880 P 7

Serial No 09/581,967, filed June 19, 2000
Docket No. 1103326-0624
Page 5 f 5

Claim 29 -Version With Markings to Show Changes Made:

29. A pharmaceutical formulation comprising therapeutically effective amounts of an IBAT inhibitor compound and a bile acid binder, wherein the [IBAT inhibitor compound is formulated for delivery of the IBAT inhibitor compound in the ileum and the] bile acid binder is coating layered for targeted release of the bile acid binder in the colon.

- 5 -

NEWYORK1020538 v1 (1ng9401).DOC (25)